October 3, 2007

Linda A. Suydam, D.P.A.
President
Consumer Healthcare Products Association
900 19th Street NW, Suite 700
Washington, DC 20006

Dear Dr. Sudyam:

I am writing regarding the documents the Consumer Health Care Products Association (CHPA) submitted to the FDA regarding the safety and efficacy of over-the-counter cough and cold medications for children and infants.[1] These documents were submitted in advance of FDA's October 18-19, 2007, advisory committee meeting at which the Agency intends to address concerns raised by a number of Maryland-based public health officials and pediatricians about these products. These experts submitted a citizen petition describing the lack of evidence to demonstrate that these products are safe and effective for young children. The petition also described injuries to children, particularly to children under six, from unintentional overdose of these products. This paucity of evidence, and risk of overdose, has led professional organizations, including the American Academy of Pediatrics and the American Academy of Chest Physicians, also to raise concerns.

I commend CHPA for providing FDA with detailed information to assist the Agency in its efforts to better understand the safety and efficacy of these pediatric products. However, I am very concerned that this evidence and CHPA's recommendations strongly suggest that a number of currently marketed products be removed from the market immediately, and that the marketing of other products be substantially modified.

Specifically, your association recommends that the labels for these products be changed to explicitly state "Do Not Use" in children under two. According to your association's document, this recommendation is based on "the challenge of obtaining pharmacokinetic data in this age group; a proportionately higher number of fatal outcomes from overdose in children

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[1] CHPA Briefing Information for Food and Drug Administration's Joint Meeting of the Nonprescription Drugs Advisory Committee & the Pediatric Advisory Committee October 18-19, 2007 (online at: http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4323b1-01-CHPA.pdf).

under two years of age; and the absence of dosing information in the OTC monograph and on the label."[2]

In direct contradiction to this recommendation, however, many CHPA member companies are currently marketing these products for use in children under two. For example, a brief internet search revealed that McNeil markets "Tylenol Infants' Drops Cold & Cough Plus Cherry Flavor" and Novartis markets "Triaminic Instant Thin Strips Decongestant Plus Cough."[3] These, and many other similar products, are clearly marketed for use in children under two. They are labeled for "infants," sold in dropper or thin strip form, and all the boxes have drawings of little babies (and no older children) on them.

The use of the term "infant" to denote the population for whom the product is intended, by itself, establishes that the product is intended for children under two. FDA's regulations state that, for purposes of drug labeling, the term "infant" means either a child under the age of one or a child under the age of two. (Manufacturers are required to qualify use of the term infant to state which of these two groups it refers to.[4]) Thus, any drug product labeled as an "infant" dosage form is clearly intended for use in children under two.

The dosage forms and strengths of some of these products also strongly suggest that they are intended only for children under two. Some products designed for "infants" can be more than three times more concentrated than the related "children's" product, because infants and children under two require a smaller volume of liquid, which must be delivered by an eyedropper.[5] Even if these concentrated products could be used in older children, it would make little sense to do so. The risk of overdose from highly concentrated dosage forms is much greater than for the less-concentrated "children's" formulations, and there is no reason to subject older children to this risk since their dosing needs can be addressed by the "children's" formulations.

Accordingly, I would like CHPA to provide me with the following:

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[2] *Id.* at 66.

[3] Concentrated Tylenol Infants' Tylenol Plus Cold & Cough webpage (online at http://www.tylenol.com/product_detail.jhtml?id=tylenol/children/prod_icpc.inc&prod=subpicpc); Triaminic Infant Thin Strips Decongestant Plus Cough webpage (online at http://www.triaminic.com/us_en/products/31916CR_relief.shtml).

[4] 21 CFR 201.19 ("Drugs; use of term "infant").

[5] E.g., Concentrated Tylenol Infants' Tylenol Plus Cold & Cough webpage (online at http://www.tylenol.com/product_detail.jhtml?id=tylenol/children/prod_icpc.inc&prod=subpicpc); Children's Tylenol Plus Multi-Symptom Cold webpage (online at http://www.tylenol.com/product_detail.jhtml?id=tylenol/children/prod_multisym_cold.inc&prod=child_multisym_cold).

1. With respect to products that are formulated and marketed specifically for infants and children under two years of age, including any products whose brand names convey that the product is for "infants," any product with a picture of a baby and no older children on it, and any products in concentrated or other formulations intended specifically for children under two, please provide an explanation for why CHPA has not recommended that its member companies discontinue the marketing of these products altogether.

2. Please provide a description of the actions CHPA intends to take to ensure that its member companies cease marketing pediatric formulations — which may be used in children up to age 12 — for use in infants and children under two years of age. Obviously, it is not enough to include the statement "Do Not Use" in children under two years of age if the packaging otherwise indicates that the product is intended to be used by exactly that population — by, for example, including "infant" in their titles and pictures of babies on their labels.

3. Please provide an explanation of what steps CHPA will take to explain to American households that the "infant" products they already have in their medicine cabinets should not be given to infants.

I appreciate that CHPA has taken a sensible position on marketing unproven cough and cold medications for use in children under two of age. However these products will remain on the shelves until the scheduled FDA advisory committee meeting — over two weeks away — and until such time when FDA takes further regulatory actions on these products. I am writing to ask for your leadership in ensuring that CHPA's recommendations are promptly carried out by your member companies in a manner that ensures that children under two are no longer exposed to cough and cold products that have not been shown to be safe and effective for them. I also ask that you take all steps necessary to ensure that the information in your possession concerning the lack of evidence supporting the use of these products is promptly conveyed to the American public so that they can make the best decisions to protect the health of their children.

I would appreciate a response by no later than October 12, 2007.

Sincerely,

Henry A. Waxman
Chairman

Enclosure

cc: Tom Davis
Ranking Minority Member